Exenatide (Byetta)
Prior Authorization Criteria for the TRICARE Pharmacy (TPHARM) Program

Background

Exenatide (Byetta) is indicated as:

- Adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione, but have not achieved adequate glycemic control.

Exenatide (Byetta) is an incretin mimetic agent that stimulates insulin production in the pancreatic islet cells when glucose levels are elevated, slows gastric emptying, and helps produce a feeling of satiety. Exenatide also reduces the secretion of glucagon, thus lowering blood glucose that are elevated after meals. It is given twice daily by subcutaneous (under the skin) injection, prior to the morning and evening meals. Exenatide should not be used as a substitute for insulin in patients who need insulin, has not been studied in patients also using insulin, and is not indicated for use in patients with type 1 diabetes mellitus. Use of exenatide as a weight loss medication in non-diabetic patients is an off-label use that is both not supported by the clinical evidence and not covered by TRICARE.

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee. These criteria have an automated component, based on review of prescriptions filled using the DoD pharmacy benefit at retail network pharmacies, military treatment facilities, or the Mail Order Pharmacy.

Prior Authorization Criteria for Exenatide (Byetta)

Coverage is approved if the patient has a diagnosis of type 2 diabetes mellitus AND meets one of the following criteria:

1. Has not achieved adequate glycemic control on at least ONE of the following
   - metformin (alone or in combination)
   - a sulfonylurea (alone or in combination)
2. Has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or a history of lactic acidosis.
3. Has experienced the following adverse event while receiving a sulfonylurea: hypoglycemia requiring medical treatment.
4. Has a contraindication to BOTH meformin and a sulfonylurea.

Automated review is performed based on ANY oral antidiabetic prescriptions, and prior metformin or sulfonylurea prescriptions, dispensed during the previous 180 days at a Military Treatment Facility (MTF), a retail network pharmacy, or the mail order pharmacy.

Criteria approved through the DoD P&T Committee process November 2010

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